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TRANSMITTAL LETTER (General – Patent Pending)	Docket No. 54084-2163

In re Application Of:
Tano, et al.

Serial No.	Filing Date	Examiner	Group Art Unit
09/761,915	January 17, 2001	BUI, Vy Q.	3731

Title:

MEMBRANE ERASER

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In re application of: Tano et al.	:	
Serial No.: 09/761,915	:	Examiner Vy Bui
Filed: January 17, 2001	:	Group Art Unit 3731
For: Membrane Eraser (Reissue Tano Patent No. 5,921,998)	:	

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313

APPEAL BRIEF

Applicants hereby submit their Appeal Brief, appealing the Final Rejection of claims 1, 3, 4, 7, 9-15, and 21-27 made in the Patent Office Action mailed July 19, 2004.

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(1) Real Party in Interest

The real party in interest in this application is Synergetics, Inc., of 3845 Corporate Centre Drive, St. Charles, Missouri 63304, by an Assignment recorded at Reel No. 010310, and Frame No. 0376.

(2) Related Appeals and Interferences

Applicant's attorneys are not aware of any related appeals and/or interferences.

(3) Status of Claims

Claims 1, 3, 4, 7, 9-15, and 21-33 are pending in the application.

Claims 28-33 have been allowed.

Claims 2, 5, 6, 8, and 16-20 have been cancelled.

Claims 1, 3, 4, 7, 9-15, and 21-27 have been given a Final Rejection.

(4) Status of Amendments

No amendments have been filed following the Final Rejection mailed July 19, 2004.

(5) Summary of the Invention

The present invention is an ophthalmic treatment tool useful for removing proliferative membranes from the neurosensory retina without injury or harm to the neurosensory retina in the treatment of proliferative vitreoretinal disorders (specification page 1, lines 3-13).

The removal of the proliferative membranes by conventional methods carries the risk of damage to the retina. Moreover, "immature proliferative membranes", common in proliferative vitreoretinal disorders, may be friable and difficult to peel off as films. These immature membranes often cannot be sufficiently removed from the surface of the retina with the conventional instruments. Consequently, the unremoved or remaining proliferative membranes are a source of subsequent reproliferation, requiring later operations for removal and correction (specification page 2, line 8-18).

With the ophthalmic treatment tool of the invention, it is possible to more appropriately separate and remove proliferative membranes, having a thin and delicate consistency, from the retina while remarkably reducing the risk of damage to the retina in the form of a retinal tear, when compared to the use of conventional instruments (specification page 3, lines 13-22).

The ophthalmic treatment tool is comprised of a grip portion 1, and a rod shaped body 2, having opposite first and second ends 20, 22. The rod first end 20 is attached to the grip portion 1. The second end 22 has a slender line portion 2' having a reduced exterior diameter from that of the remainder of the rod shaped body 2. The exterior diameter of the slender line portion 2' is preferably in a range of 0.4 mm to 0.6 mm and the exterior diameter of the remainder of the rod shaped body 2 is preferably in a range of 0.9 mm to 1.2 mm. The slender line portion 2' is configured to receive an elastic body 3 fitted thereon. The elastic body 3 surrounds and extends beyond the slender line portion 2'. The elastic body 3 is provided with a tapered tip 4, having a group of hard, inorganic fine grain particles 5 fixed thereon (specification page 4, line 32-page 5, line 11).

The grip 1 is adapted to be securely grasped by a user's fingers during surgery. The grip 1 is suitably formed to be as thick as common items, which the user is generally accustomed to handling, such as a pencil or pen. Preferably, metal is used for the grip (specification page 5, lines 12-25).

The rod shaped body 2 extends from the distal end 10 of the grip. The rod shaped body is provided for purposes of supporting the elastic body 3, which is placed on the slender line portion 2' of the second end 22 of the rod shaped body 2. Similar to the grip, the rod shaped body is made from a material which presents no hygienic problems (specification page 5, line 32-page 6, line 7).

The elastic body 3 is translucent and takes the form of a tube, which is fixed to the rod shaped body by being inserted on the slender line portion 2'. The slender line portion 2' is squeezed into a tube shaped opening 33 in the elastic body 3, whereby the bodies 2, 3 are fixed to each other. The manner of coupling both, however, should not be restricted to the configuration shown in the figures, and any type of coupling can be applied to the bodies with a tight coupling of the rod shaped body 2 and the elastic body 3 resulting (specification page 6, lines 12-25).

The elastic body 3 may be made from any material which presents no sanitary problems. Preferably, the elastic body is made from silicone rubber in light of its pliability and inertness (sanitary property). The slender line portion 2' is not entirely inserted through the tube of the elastic body 3 but stops short, leaving a portion of the tube projecting from the second end 22 of the rod to the tapered tip 4 of the elastic body 3. A portion of the tube of the elastic body 3 projecting from the rod end 22 gives the elastic body a sufficient pliability and a flexible distal end so as not to carry the risk of

causing damage to the retina when peeling membranes from the retina during ophthalmic surgery (specification page 6, line 26-page 7 line 12).

The tip 4 of the elastic body 3 is formed in a tapered shape. The shape can be easily formed by cutting the tube shaped elastic body at a bevel. However, such a profile is not essential for the present invention. For instance, an elastic body having no tube like opening for insertion of the slender line portion 2' will not have a tubular extension projecting from the slender line portion 2' of the rod shaped body. In this instance, the tip of the elastic body 3 should be tapered only (specification page 7, lines 13-26).

Numerous hard inorganic fine grains 5 are bonded to the tapered tip 4 of the elastic body 3. The fine grains 5 are provided around the tip 4. The fine grains 5 function to peel and remove the proliferative membranes on the retina without injury to the retina. The hard inorganic fine grains used on the tip 4 may consist of any rigid fine grains or particles which have chemical inertness and present no problem in sanitation. For example, the fine grains may be various kinds of fine grains such as diamond, diamond like carbon, ruby, sapphire, quartz, crystal, alumina, silica, silicone carbide, silicone nitride, marble, grindstone, or the like. The find grains 5 are preferably made of diamond in light of the chemical inertness and the advantages associated with hygiene (specification page 7, line 27-page 8, line 7).

The fine grains 5 may range in size or diameter from 3 μm to 80 μm, and preferably range between 9 μm and 30 μm. It has been found that proliferative membranes on the retina would not be sufficiently removed at any rate if the diameter of the grains are out of this range (specification page 8, lines 8-12).

The method used to bond the fine grains 5 to the elastic body is preferably performed by using an adhesive chosen in accordance with the nature of the material of the elastic body 3. If the elastic body is made from silicone rubber, a silicone base adhesive is preferably used. A bonding of the hard inorganic fine grains can be performed in many well known ways. However, it is desirable that the surfaces of the fine grains are exposed externally and not covered with the adhesive. Preferably, the bonding of the fine grains is performed as follows: first, an appropriate adhesive is attached to the tip of the elastic body; secondly, the hard an organic fine grains are dispersed on a surface of the attached adhesive to cover the surface; thirdly, a process is performed whereby the adhesive constructs bridges from the elastic body to the fine grains and hardens. This process is repeated until the desired coarseness is achieved on the elastic body to allow the fine grains to effectively remove proliferative membranes. Following the completion of the process of constructing bridges and hardening of the adhesive, it is preferable to remove fine grains loosely attached to the tip of the elastic body (that is, fine grains which may come off the tip during an ophthalmic surgery) by performing an ultrasonic cleaning or similar process (specification page 8, line 13-page 9, line 16).

Although Figure 1c shows an example of a range that the hard inorganic fine grains 5 are fixed to the tapered portion 4 of the elastic body 3, the example is merely one example. The removal of proliferative membranes using the instrument of this invention may require different ranges. The range (x), which has been obtained based on experiment and seems to be preferable has a width between 0.5 and 3 mm. It should be noted that some measurements inscribed in the Figures do not limit the

present invention, but are displayed for those skilled in the art to easily understand the invention. Further note that Figure 2 shows an ophthalmic treatment tool of the other embodiment according to the present invention (specification page 9, lines 13-33).

The treatment tool embodying the present invention differs from rigid instruments such as picks and forceps applying mechanical force to the synechia portion between the proliferative membranes and the retina. The treatment tool has a slender profile and a flexible front tip to permit increased visualization of the area of interest in an ocular tissue during a surgery, enabling the treatment to be performed properly and easily (specification page 11, lines 5-13).

(6) Issues

Issue I

Is the membrane eraser of claim 26 fully anticipated by the disclosure of the Varaine Patent No. 5,118,291 for an instrument for removing deposits and stains on teeth where the reference does not fully disclose the instrument tip that is used for the removal of membrane tissue of a retina recited in claim 26?

Issue 2

Is the subject matter of claims 1, 3, 4, 7, 9-15, and 21-27 an attempt to improperly recapture broadened claimed subject matter surrendered in the prosecution of the application for the patent where the interpretation of what was surrendered in the prosecution of the application is inaccurate?

(7) Grouping of Claims

Independent claims 1, 9, 12, 21, and 26 are separately patentable and arguments on the patentability of each of these claims are presented herein.

Claims 3, 4, and 7 stand or fall with claim 1.

Claims 10 and 11 stand or fall with claim 9.

Claims 13-15 stand or fall with claim 12.

Claims 22-25 stand or fall with claim 21.

Claim 27 stands or falls with claim 26.

(8) Argument

Rejection Under 35 U.S.C. § 102

Claim 26 of the application was given a final rejection under 35 U.S.C. § 102 in view of the disclosure of the U.S. patent of Varaine No. 5, 118,291. However, the Varaine patent does not disclose the subject matter of the invention recited in claim 26, and therefore the disclosure of the patent fails to anticipate that subject matter.

It is a fundamental tenet of patent law that an anticipation rejection requires identity of the invention in the prior art relied on in rejecting the claims.

> For a prior-art reference to anticipate, every element of the claimed invention must be identically shown in a single reference. In re Bond, 910 F.2d. 831, 15 U.S.P.Q. 2d. 1566 (Fed. Cir. 1990).

Among the novel features of the invention recited in claim 26, the claim includes the features of a "membrane eraser used for a ophthalmic surgery" having "a plurality of

hard, inorganic fine grains...located in a range from an end portion of a front tip for removal of membrane tissue on a retina of an individual". The subject matter of claim 26 recited above is found in both the preamble of the claim and in the counts of a claim.

In contrast to the above, the Varaine referenced discloses an instrument used in cleaning teeth. The Varaine reference does not identically show the "membrane eraser used for ophthalmic surgery" having a plurality of fine grains that are located in a range from an end portion of the eraser tip "for the removal of membrane tissue on a retina" as set forth in claim 26. The reference clearly does not identically show every element of the claimed invention as required by the above case law. The Varaine instrument is not a membrane eraser, and does not have fine grains located on a tip for removing retinal membranes. It is therefore submitted that the rejection of claim 26 as being anticipated by the Varaine referenced is made in error and should be reversed and the claim allowed.

Claim Rejections Under 35 U.S.C. § 251

Claims 1, 3-4, 7, 9-15, and 21-27 were rejected under 35 U.S.C. § 251 as being an improper recapture of claimed subject matter that was surrendered in the prosecution of the application for the patent upon which the present reissue application is based.

In the rejection it is contended that claim 1 of the original patent application was amended to recite "a hollow tapered front tip" and "grains are located in a range of 0.5 mm to 3.0 mm from an end portion of said front tip" to overcome an anticipation rejection in view of the U.S. Patent of Shimizu No. 3,809,101. It is also contended that an argument was presented in the prosecution of the patent application that the Shimizu

patent does not disclose the two features cited above, and therefore amended claim 1 was defined over Shimizu. The rejection states that the omission of the features quoted above from independent claims 1, 9, 12 and 21 of the present application presents an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue application is based.

It is respectfully submitted that the above set forth recount of the prosecution history of the patent upon which the present reissue application is based is not accurate. Claim 1 was amended to recite "a hollow tapered front tip" and "said grains are located in a range of 0.5 mm to 3.0 mm from an end portion of said front tip" among other amendments made to the claim. However, the representation of the arguments made during the application prosecution is not accurate. The argument distinguishing the Shimizu reference stated that the subject matter claimed was:

> "clearly distinguished from the nail file filing an individual's nails as shown in Shimizu which neither comprises a hollow tapered front tip of an elastic body nor does the same teach limiting the location of the grains to the range presently claimed and instead teaches only the utilization of an abrasive sheet 9 which extends substantially the entire length of the holding member".

There is no mention of the specific 0.5 mm to 3.0 mm range in the prosecution argument distinguishing the Shimizu reference. Thus, there is no evidence in the prosecution history that the specific range of 0.5 mm to 3.0 mm was added to claim 1 to distinguish the subject matter claimed from Shimizu. The only evidence provided by the

REMARKS portion of the amendment states that Shimizu neither comprises a hollow tapered front tip nor teaches limiting the location of the grains to a range.

> "Reissued claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule." In re Clement, 131 F. 3d. 1464, 1470, 45 U.S.P.Q. 2d 1161, 1165 (Fed. Cir. 1997).
>
> The recapture rule does not apply where there is no evidence that amendment of the originally filed claims was in any sense an admission that the scope of that claim was not in fact patentable. Seattle Box Co. v. Industrial Crating and Packaging, Inc., 731 F. 2d 818, 826, 221 U.S.P.Q. 568, 574 (Fed. Cir. 1984).

There is no evidence presented that the limitation of 0.5 mm to 3.0 mm was added to claim 1 of the original patent application to avoid the Shimizu reference. Claim 1 was amended to include the limitation of the grains being located in a range from an end portion of the front tip to distinguish the subject matter of the invention from the Shimizu reference. As set forth in the REMARKS, the Shimizu nail file did not teach limiting the location of the grains to the range, but instead teaches only the utilization of an abrasive sheet which extends substantially the entire length of the holding member of the nail file. There was no argument that the specific 0.5 mm to 3.0 mm range was patentable, only that a range, distinguished from the entire instrument length, was patentable. Thus, it is not necessary that the independent claims of the reissue application include in their limitations the specific 0.5 mm to 3.0 mm range.

Claim 1 of the application includes the limitation of the fine-grains being located in a range from an end portion of the tip. Claim 9 includes the limitation of the fine-

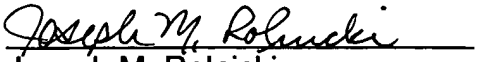
grains being located in a range from an end portion of the tip. Claim 12 includes the limitation of the elastic body having a hollow, generally tubular shape, and the fine-grains being located in a range on said distal end portion of the elastic body. Claim 21 includes the limitations of a flexible tapered tip and the fine-grains being fixed to the elastic portion of the tool located in a range from an end portion of the tapered tip.

It is respectfully submitted that claims 1, 9, 12 and 21 and their dependent claims 3, 4, 7, 10, 11, 13-15, and 22-25 are in conformance with 35 U.S.C. §251, and the rejections of the claims should be reversed and the claims allowed.

Claim 26 conforms to the language of claim 1 of the issued Patent No. 5,921,998 except for the absence of the word "hollow" in describing the tapered front tip and the absence of the words "of 0.5 mm to 3.0 mm" in describing the range of the fine-grains. For the reasons set forth above with regard to claim 1, it is respectfully submitted that the rejections of claim 26 and its dependent claim 27 are made in error and should be reversed and the claims allowed.

(10) Conclusion

For the reasons set forth herein, it is respectfully submitted that the Final Rejections of claims 1, 3, 4, 7, 9-15, and 21-27 are made in error and should be reversed and the claims allowed.



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(9) Appendix

1. A membrane eraser used for ophthalmic surgery, comprising:

a grip portion;

a rod shaped body having opposite first and second ends, said first end being attached to [[one end of]] said grip portion, said second end extending away from said grip portion;

an elastic body having opposite proximal and distal ends and a hollow interior, said hollow interior at said proximal end receiving said second end of said [[fitted along a direction toward a front end of said]] rod-shaped body, said distal end having a tapered tip extending away from said rod shaped body [[to the front end side thereof and having a hollow tapered front tip]]; and

a plurality of hard, [[inorganic]] fine-grains fixed on said tapered [[front]] tip of said elastic body, said fine-grains being located in a range from an end portion of said tip, said fine-grains being configured [[wherein said grains are located in a range of .05 mm to 3.0 mm from an end portion of said front tip]] for removal of membrane tissue on a retina of an individual.

2. (Cancelled).

3. A membrane eraser according to claim 1, wherein said hard [[inorganic]] fine-grains comprise grains having a range in diameter from 3 μm to 80 μm.

4. A membrane eraser according to claim 1, wherein said hard [[inorganic]] fine-grains comprise diamond particles.

5. (Cancelled).

6. (Cancelled).

7. A membrane eraser according to claim 1, wherein said grains are located in a range of 0.5 mm to 3.0 mm from said distal end of the elastic body.

8. (Cancelled).

9. An ophthalmic treatment tool comprising:

a grip;

a rod shaped body having opposite first and second ends, said first end attached to said grip, said second end extending away from said grip;

an elastic body attached to said second end of said rod shaped body, said elastic body having a tapered tip extending away from said rod shaped body;

a plurality of hard, fine-grains fixed on said tapered tip of said elastic body, said fine-grains being located in a range from an end portion of said tip; and

said elastic body has a general cylindrical shape with opposite proximal and distal ends and a hollow interior, said proximal end is fitted onto said second end of said rod shaped body, said distal end is cut on a bevel forming said tapered tip.

10. The ophthalmic treatment tool according to claim 9 wherein said rod shaped body has a slender line portion at said second end, the elastic body is fitted on said slender line portion.

11. The ophthalmic treatment tool according to claim 10 wherein said slender line portion is formed in an angle relative to said rod shaped body.

12. An ophthalmic treatment tool comprising:

a grip;

a rod shaped body having opposite first and second ends, said first end attached to said grip, said second end having a slender line portion extending away from said grip;

an elastic body having a hollow, generally tubular shape with opposite proximal and distal ends, said proximal end having an opening receiving said slender line portion therein, said second end being spaced from said slender line portion and extending to a distal end having a taper; and

a plurality of hard, fine-grains fixed on said distal end of said elastic body, said fine-grains being located in a range on said distal end portion.

13. The ophthalmic treatment tool according to 12 wherein said slender line portion is formed in an angle relative to said rod shaped body.

14. The ophthalmic treatment tool according to claim 12 wherein said fine-grains are located in a range of 0.5 mm to 3.0 mm from a distal end of the elastic body.

15. The ophthalmic treatment tool according to claim 12 wherein said fine-grains have a range in diameter from 3 μm to 80 μm.

16-20. (Cancelled).

21. An ophthalmic membrane eraser comprising:

a tool having a length with opposite proximal and distal ends, a rigid portion of the tool adjacent the tool proximal end and an elastic, flexible tapered tip portion of the tool adjacent the tool distal end, the elastic portion of the tool is attached to the rigid portion of the tool and projects from the rigid portion of the tool for a portion of the length of the tool to the tool distal end, the elastic portion of the tool has a tapered tip at the tool distal end; and

a plurality of hard, fine-grains fixed to the elastic portion of tool, the fine-grains are fixed to the elastic portion of the tool only located in a range from an end portion of the tapered tip and are absent from a remainder of the elastic portion of the tool so as not to detract from the flexibility of the remainder of the elastic portion of the tool.

22. The membrane eraser of claim 21, wherein:

the elastic portion of the tool is flexible along the portion of the length of the tool that the elastic portion projects from the rigid portion.

23. The membrane eraser of claim 21, wherein:

the plurality of hard, fine-grains are fixed to only an exterior surface of the elastic portion of the tool adjacent the distal end of the tool.

24. The membrane eraser of claim 21, wherein:

the rigid portion of the tool includes a grip at the tool proximal end and a rod-shaped body attached to the grip and projecting from the grip.

25. The membrane eraser of claim 21, wherein:

the elastic portion has a beveled surface adjacent the distal end of the tool and the hard, fine-grains are fixed only on the beveled surface.

26. A membrane eraser used for ophthalmic surgery, comprising:

a grip portion;

a rod shaped body attached to one end of said grip portion;

an elastic body fitted along a direction toward a front end of said rod shaped body to the front end side thereof and having a tapered front tip; and,

a plurality of hard, inorganic fine-grains fixed on said tapered front tip of said elastic body wherein said grains are located in a range from an end portion of said front tip for removal of membrane tissue on a retina of an individual.

27. A membrane eraser according to Claim 26, wherein said fine-grains are located in a range of 0.5 mm to 3.0 mm.

28. A membrane eraser used for ophthalmic surgery, comprising:

a grip portion;

a rod shaped body attached to one end of said grip portion;

an elastic body fitted along a direction toward a front end of sad rod shaped body to the front end side thereof and having a tapered front tip;

a plurality of hard, inorganic fine-grains fixed on said tapered front tip of said elastic body wherein said grains are located in a range from an end portion of said front tip for removal of membrane tissue on a retina of an individual;

said fine-grains are located in a range of 0.5 mm to 3.0 mm; and,

said tapered front tip is hollow.

29. A membrane eraser according to Claim 28, wherein said elastic body comprises silicone rubber.

30. A membrane eraser according to Claim 28, wherein said hard inorganic fine-grains comprise grains having a range in diameter from 3 to 80 μm.

31. A membrane eraser according to Claim 28, wherein said hard inorganic fine-grains comprise diamond particles.

32. A membrane eraser according to Claim 28, wherein said rod shaped body comprises titanium.

33. A membrane eraser according to Claim 28, wherein said hard inorganic fine-grains are fixed by a silicone base adhesive to said front tip.